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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,660	03/19/2001	Roman Efrain Vasquez Lipi	2119-109	9057
6449	7590	04/15/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,660

Applicant(s)

VASQUEZ LIPI, ROMAN EFRAIN

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-15, 17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-15, 17, 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of response filed on December 16, 2004. Claim rejection made under 35 U.S.C. § 112, second par., as indicated in the previous Office action dated June 16, 2004, is withdrawn in view of claim cancellation made by applicant. Claim rejection made under 35 U.S.C. § 103(a) over George (US 3431340) in view of Soto (Derwent Acc. No. 1984-271531), Arhens (US 3825563), Kaplan (US 5047232), and Slimak (US 6099866), as indicated in the same Office action, is maintained for the reasons of record. Claim rejection made under 35 U.S.C. § 103(a) over the combined references and further in view of Martin (US 5874479) is withdrawn and modified to address the claim amendment made by applicant. Claims 1, 2, 4-15, 17, and 22-27 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 2, 4-15, 17, 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over George (US 3431340) in view of Soto (Derwent Acc. No. 1984-271531), Arhens (US 3825563), Kaplan (US 5047232), and Slimak (US 6099866).

George teaches that castor oil and cod liver oil are well known for the treatment of burns. See col. 2, lines 1 – 61. The reference teaches a topical composition consisting essentially of 35-65 % by weight of castor oil and 35-65 % by weight of cod liver oil. The reference recites, “[t]he castor oil prevents the growth of scar tissue, and the fish oil controls the caustic action of the castor oil,

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while at the same time promoting the healing of the wounds.” See col. 2, lines 45 – 48; see also col. 2, lines 15 – 26. The reference also teaches that cod liver oil contains at least 1000 USP units of vitamin A and 100 USP units of vitamin D per gram. See col. 2, lines 21 – 26. The reference further teaches that “[a]dditional quantities of vehicles, vitamins, and other fortifying substances may be as required.” See col. 2, lines 9-14. See instant claims 6-8, 10-13.

George fails to teach the remaining components recited in claim 1.

Soto teaches method of treating skin injuries by topically applying a composition comprising essentially of olive oil (100 parts) and beeswax (10 parts) as the principal ingredients. See abstract. The reference also teaches that one of more aromatic plant oils can be further incorporated therein.

Ahrens teaches a vitamin E (d-alpha-tocopheryl-acid-succinate) cream compositions having sweet almond oil and mineral oil (petrolatum) base. The reference teaches that the compositions provide stable and economic means to provide the therapeutic effects of vitamin E. See the amounts of the ingredients in Tables 1, 2, and 3. See instant claim 17. The reference specifically teaches that the application of Vitamin E to burn skin “immediately” relieved pain, renewed the skin layers afterwards and provided healing effects on the third day. See col. 8, lines 7 – 21. See instant claims 9, 14, and 15.

Kaplan teaches that almond oil and castor oil are emollients well known to one having ordinary skill in the art. See col. 3, lines 66-67; col. 4, lines 34 – 3. Specific examples that these oils are used in mineral oil-based composition are shown in Examples 1, 2, 3, and 13. See instant claim 17. The examples also

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employ vitamin E in the weight amount of 0.1 -1 % by weight. See instant claim 9.

Slimak teaches a composition comprising beeswax and oil, with or without water, useful for treating topical wounds including burns. See abstract. The reference specifically provides motivation to limit the ingredients to wax, oil, and water, due to possibility of allergic reactions. See col. 12, lines 37 – 43. The reference teaches that antibiotics may be added. See col. 13, lines 10 – 17. See instant claim 22. Slimak teaches to combine the beeswax with plant oils and suggest that animal oil can be further added therein. See col. 12, lines 16 – 44. Almond, olive, sunflower, and mineral oils are disclosed. It is well known in the art that sunflower oil also contains vitamin E. The reference further teaches that “an oil similar to the plant source of the wax” is preferably used, which include sunflower and olive oils. Accordingly, a skilled artisan would have been motivated to select these oils to combine with the beeswax composition. The Slimak reference teaches when water, the excipient in this case, is used, the volume ratio of wax:oil:water can range from 1:0.1:0 to 1:6:6 to produce a soft, easily applicable composition for topical application to the skin. See col. 10, lines 55 – 60. See instant claim 2.

While the specific weight amount of the each of oil components are not taught as recited in the instant claim, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the

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combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable weight amount of the ingredients by routine experimentation. The skilled artisan would have considered the cost of the ingredients or the rheology or spreadability of the final product, as suggested by Slimak. See col. 10, lines 55 – 60. See also In re Boesch, 205 U.S.P.Q. 215 (C.C.P.A. 198) (holding it is within the skill in the art to select optimal parameters, such as amount)

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings in the George, Soto, Ahren, and Kaplan. As shown by the references, the instant claims define the concomitant use of conventional therapeutic agents known for burn treatment. It would follow that the combination of beeswax, olive oil, castor oil, and cod liver oil and the method of use thereof is prima facie obvious.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the George composition by adding the additional ingredients of the secondary references because

- 1) all references are directed to burn skin treatment compositions;
- 2) George specifically teaches to further incorporate “vehicles, vitamins, and other fortifying substances” to the castor oil/cod liver oil composition;

3) the skilled artisan would have had expectation that addition of olive oil and beeswax have additive effect in burn skin treatment composition, as taught by Soto;

4) the skilled artisan would have expected that further addition of petrolatum and almond oil to mix with vitamin E composition produces a stable therapeutic composition with enhanced healing effect on burn skin, as taught by Ahren;

5) the skilled artisan would have also expected that using natural oil such as sunflower oil for beewax and further adding preservative would successfully produce a further stable burn treatment composition with an enhanced effectiveness, as taught by Slimak.

2. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over George, Soto, Arhens, and Slimak as applied to claims 1, 2, 4-15, 17, 24-27 above, and further in view of Martin (US 5874479).

The combined references fail to teach butylhydroxytoluene (BHT).

Martin teaches topical wound-healing compositions useful for, among others, healing of burns. See col. 23, lines 1 –9. The reference teaches that BHT is an art-recognized preservative. See col. 13, lines 53-54. See instant claim 23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding BHT in the composition because Martin teaches that BHT is a conventional preservative well known in pharmaceutical art. The skilled

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artisan would have had a reasonable expectation of successfully producing a skin treatment composition with longer shelf-life because Slkimak teaches to add a preservative and the compositions of the combined references and Martin are topical formulations.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4-15, 17, and 22-27 have been considered but are unpersuasive.

Applicant argues that the cod fish oil of the George reference is used as a vehicle, which is not the purpose of which the ingredient is used in the present invention. Applicant also asserts that the present invention differs from the prior art in that the present invention uses beeswax, petroleum jelly and stearic acid as the vehicle. The argument is unpersuasive because whether cod liver oil is used as a vehicle or main active ingredient does not render the composition itself nonobvious. Furthermore, the reference even teaches that cod liver oil is loaded with vitamin A and D which provides ample motivation for a skilled artisan to use the oil.

Applicant also asserts that the secondary references merely teach that the recited components are "well known and commonly used in the art". Examiner respectfully disagrees. As fully discussed in the rejection, the obviousness rejection made in this case is based on the objective and specific findings in the references that teach the functions and purposes for which the applicant's components are used in skin treatment compositions for skin injuries and burn wounds. It is these specific functions of the each ingredient (e.g., pain reliever,

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emollient, preservative, etc.) which would have given the routineer motivation to combine the references, and not the mere notion that these components are well known and commonly used in skin care art.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

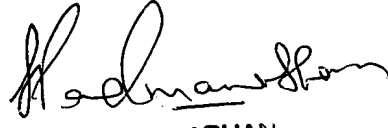
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



SREENI PALMANABHAN
SUPERVISORY PATENT EXAMINER